

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: MERCK MUMPS	:	Master File No. 2:12-cv-03555
VACCINE ANTITRUST	:	
LITIGATION	:	CLASS ACTION
	:	<u>JURY TRIAL DEMANDED</u>
THIS DOCUMENT RELATES TO:	:	
ALL ACTIONS	:	
	:	

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

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Plaintiffs Chatom Primary Care, P.C., Andrew Klein, M.D., and John I. Sutter, M.D., on behalf of themselves and all others similarly situated, bring this action against Merck & Co., Inc. (“Merck” or “Defendant”), and allege as follows, based on information and belief, plaintiffs’ counsel’s investigation, and a *qui tam* action filed by Stephen A. Krahling and Joan A. Wlochowski (the “Relators”) captioned *Krahling v. Merck & Co., Inc.*, Case No. 2:10-cv-04374-CDJ (E.D. Pa.) (the “*Qui Tam* Action”):

INTRODUCTION

1. In 2006, and then again in 2009, the largest mumps outbreaks in two decades occurred in the United States in a highly vaccinated population. According to leading experts and an article published in *The New England Journal of Medicine*, these “unexpected” outbreaks were characterized by “two-dose vaccine failure.” Thus, it was declared that “[a] more effective mumps vaccine or changes in vaccine policy may be needed to avert future outbreaks and achieve the elimination of mumps.”

2. Although these outbreaks took physicians and the scientific community by surprise, Merck, the exclusive supplier of the mumps vaccine (including M-M-R®II and ProQuad®) (collectively, “Mumps Vaccine”) in the U.S., knew for at least a decade that its vaccine was far less effective than it claimed.

3. This lawsuit is brought as a putative class action against Merck for, among other violations, unlawfully monopolizing the U.S. market for Mumps Vaccine by engaging in a decade-long scheme to falsify, misrepresent, and conceal the true efficacy of its vaccine.

4. Specifically, Merck fraudulently represented and continues to falsely represent in its labeling and elsewhere that its Mumps Vaccine has a “high degree” of efficacy with at least a 95 percent efficacy rate.

5. Merck manufactures its Mumps Vaccine using an attenuated virus. An attenuated virus is created when its pathogenicity has been reduced so that it will initiate an immune response without producing the specific disease. Pathogenicity is reduced by “passaging” the virus through a series of cell cultures or animal embryos. With each passage, the virus becomes better at replicating in the host, but loses its ability to replicate in human cells. Eventually, the attenuated virus will be unable to replicate well (or at all) in human cells, and can be used in a vaccine. When this vaccine is administered to a human, the virus in it will be unable to replicate enough to cause illness, but will still provoke an immune response that can protect against future infection.

6. Merck knew and understood that continued passaging of the attenuated virus from which its Mumps Vaccine was created (over forty years ago) had altered the virus and degraded its efficacy.

7. For a variety of reasons, including Merck's development and quest for approval of a new combination vaccine that contained its Mumps Vaccine, Merck initiated new efficacy testing of its Mumps Vaccine in the late 1990s. As demonstrated below, the goal of this new efficacy testing was to support its original efficacy findings at all costs, including the use of scientifically flawed methodology and falsified test results.

8. First, Merck designed a testing methodology that evaluated its vaccine against a less virulent strain of the mumps virus. After the results failed to yield Merck's desired efficacy, Merck abandoned the methodology and concealed the study's findings.

9. Merck then designed another even more scientifically flawed methodology, this time incorporating the use of animal antibodies to artificially inflate the results, but this methodology too failed to achieve Merck's desired efficacy rate. Confronted with two failed

methodologies, Merck then falsified the test data to obtain the results it desired. Having reached the desired, albeit falsified, efficacy threshold, Merck submitted these fraudulent results to the U.S. Food & Drug Administration (“FDA”) and European Medicines Agency (“EMA”).

10. Merck took steps to cover up the tracks of its fraudulent testing by destroying evidence of the falsified data and then lying to an FDA investigator that questioned Merck about its ongoing testing. Merck also attempted to buy the silence and cooperation of its staff by offering them financial incentives to follow the direction of the Merck personnel overseeing the fraudulent testing process. Merck also threatened a relator in the *Qui Tam* Action, Stephen Krahling, a virologist in Merck’s vaccine division from 1999 to 2001, with jail if he reported the fraud to the FDA.

11. Merck continued to conceal what it knew (or should have known) about the diminished efficacy of its Mumps Vaccine even after the U.S. experienced the largest mumps outbreaks in two decades in 2006 and 2009. Merck has known for over a decade that its Mumps Vaccine is far less effective than it claims. As Merck profited from its unlawful scheme, health care providers around the country have purchased millions of doses of Mumps Vaccine, with questionable efficacy, at artificially inflated prices.

PARTIES

12. Plaintiff, Chatom Primary Care, P.C., is an Alabama corporation. During the Class Period (defined below), Chatom Primary Care, P.C. purchased the Mumps Vaccine from Merck at artificially inflated prices.

13. Plaintiff, Andrew Klein, M.D., is a resident of the State of New York. During the Class Period (defined below), Dr. Klein purchased the Mumps Vaccine from Merck at artificially inflated prices.

14. Plaintiff, John I. Sutter, M.D., is a resident of the State of New Jersey. During the Class Period (defined below), Dr. Sutter purchased the Mumps Vaccine from Merck at artificially inflated prices.

15. Defendant Merck is a New Jersey corporation with its vaccine division based in West Point, Pennsylvania. Merck—either directly or through its subsidiaries, which it wholly owned or otherwise controlled—manufactured, marketed and sold Mumps Vaccine that was purchased throughout the United States, including in this District, during the Class Period. Merck is one of the largest pharmaceutical companies in the world with annual revenues exceeding \$20 billion. Merck is also a leading seller of childhood vaccines and currently markets in the U.S. vaccines for 12 of the 17 diseases for which the Centers for Disease Control and Prevention (“CDC”) currently recommends vaccination.

16. Merck is the sole manufacturer licensed by the FDA to sell Mumps Vaccine in the U.S. Merck’s Mumps Vaccine, together with Merck’s vaccines against measles and rubella are sold as M-M-R®II. Merck annually sells more than 7.6 million doses of M-M-R®II in the U.S. for which it derives hundreds of millions of dollars of revenue. Merck also has a license in the U.S. to sell ProQuad®, a combination vaccine containing M-M-R®II vaccine and chickenpox vaccine. Under a license from the EMA, Merck also sells Mumps Vaccine in Europe as a part of M-M-RVaxpro® and ProQuad® through Sanofi Pasteur MSD, a joint venture with the vaccine division of the Sanofi Aventis Group. Since its approval in 2005, and until 2010, ProQuad® has been sold intermittently in the U.S. and Europe.

JURISDICTION AND VENUE

17. The federal law claims set forth in this Consolidated Amended Complaint arise under Section 2 of the Sherman Antitrust Act, 15 U.S.C. § 2. Plaintiffs seek treble damages

pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15(a). Plaintiffs also assert claims for actual and exemplary damages pursuant to state consumer protection, contract and warranty laws, and common law unjust enrichment, and seek to obtain restitution, recover damages and secure other relief against Defendant for violations of those laws. Plaintiffs and the Class (defined below) also seek attorneys' fees, costs, and other litigation expenses permitted under federal and state law.

18. This Court has jurisdiction pursuant to Sections 4 and 12 of the Clayton Act, 15 U.S.C. §§ 15(a) and 22, and pursuant to 28 U.S.C. §§ 1331 and 1337.

19. This Court also has subject matter jurisdiction of the state law claims pursuant to 28 U.S.C. § 1332(d), in that this is a class action in which the matter or controversy exceeds the sum of \$5,000,000, exclusive of interests and costs, and in which some members of the Class are citizens of a state different from Defendant.

20. This Court also has supplemental jurisdiction of the state law claims asserted herein pursuant to 28 U.S.C. § 1337 because they are so related to the claims asserted in this action over which this Court has original jurisdiction that they form part of the same case or controversy.

21. Venue is proper in this District pursuant to Sections 4 and 12 of the Clayton Act (15 U.S.C. §§ 15(a) and 22) and 28 U.S.C. § 1391(b) and (c) because the Defendant can be found in and transacts business within this District, and a substantial part of the events or occurrences giving rise to the claims alleged occurred in this District. Indeed, Merck's fraudulent scheme to maintain and further its monopoly power was originated and continues to be carried out in this District at Merck's vaccine division facility in West Point, Pennsylvania.

INTERSTATE COMMERCE

22. Throughout the Class Period, Merck manufactured, produced, sold and/or shipped substantial quantities of Mumps Vaccine in a continuous and uninterrupted flow of transactions in interstate commerce throughout the U.S., including within this District. Merck's unlawful activities that are the subject of this Consolidated Amended Complaint were within the flow of, and have had a direct and substantial effect on, interstate trade and commerce.

FACTUAL BACKGROUND

A. The Market for Mumps Vaccine Has And Continues To Be Dominated By A Single Manufacturer – Merck

1. Background On The Mumps Vaccine

23. Mumps is a contagious viral disease characterized by fever, headache, muscle weakness, loss of appetite, and swelling of one or more of the salivary glands. Although severe complications are rare, the mumps virus can cause inflammation of the brain and spinal cord (among other organs), sterility, and deafness.

24. Merck first obtained approval for the Mumps Vaccine in 1967 from Department of Biologics Standards of the National Institute of Health (“DBS”), the government agency at the time responsible for licensing vaccines. The vaccine was developed by Dr. Maurice Hilleman, at Merck’s West Point research facility, from the mumps virus that infected his five year-old daughter, Jeryl Lynn. Merck continues to use this “Jeryl Lynn” strain of the virus for its vaccine today.

25. Merck’s original Mumps Vaccine was delivered to patients in a single, stand-alone injection called Mumpsvax®. In 1971, Merck developed the M-M-R® combination vaccine (incorporating vaccines for measles and rubella with the Mumps Vaccine into a single injectable) and that same year obtained DBS approval to manufacture and sell the M-M-R®

vaccine in the U.S. In 1978, Merck obtained approval from the FDA (which succeeded the DBS as the agency responsible for licensing vaccines) for the manufacture and sale of M-M-R®II, a replacement for M-M-R® containing a different strain of the rubella virus. Since that time, Merck has sold more than 450 million doses of M-M-R®II world-wide, with approximately 200 million of those doses sold in the U.S.

26. In September 2005, Merck obtained FDA approval for ProQuad®, a multi-disease vaccine that includes vaccinations for mumps, measles, rubella and chicken pox in a single injection. Merck sold ProQuad® in the U.S. from the time of its approval in 2005 until June 2007. According to Merck, the vaccine became unavailable because of certain manufacturing constraints. The vaccine was briefly available again in 2010 but has not been available since then.

2. The U.S. Market For Mumps Vaccine And Merck's Monopoly Power

27. As the only company licensed by the U.S. Government to sell Mumps Vaccine, Merck has had a monopoly and continues to have a monopoly in the U.S. market for Mumps Vaccine since it obtained its original license in 1967. This has extended to multi-disease vaccines such as M-M-R®, M-M-R®II, and ProQuad®. However, Merck has maintained this monopoly not through its legitimate business acumen and innovation or its manufacture and sale of the safest, most effective, and most cost-effective Mumps Vaccine in the market. Instead, Merck has willfully and illegally maintained its monopoly through its ongoing manipulation of the efficacy of its Mumps Vaccine. Through this unlawful conduct, Merck has been able to monopolize the Relevant Market (defined below) by both representing to the public and government agencies a falsely inflated efficacy rate for its Mumps Vaccine and concealing what it knew about its Mumps Vaccine's diminished efficacy, all to the detriment and exclusion of potential competitors in the Market.

(a) The Relevant Geographic Market Is The U.S.

28. The U.S. (including all U.S. territories and commonwealths) is the relevant geographic market in this case. Merck manufactures and distributes its Mumps Vaccine throughout the U.S. The unlawful and anticompetitive conduct at issue in this case affects only U.S. sales of the relevant products. Mumps Vaccine requires FDA licensing before it can be sold in the U.S.

(b) The Relevant Product Market Is The Market For Mumps Vaccine

29. The U.S. sale of Mumps Vaccine (including without limitation M-M-R®II and ProQuad®) (the “Relevant Market”) is the relevant product market in this case.

(c) Barriers To Entry Are High In The Mumps Vaccine Market

30. There are significant barriers to entry inherent in the manufacture and sale of a new vaccine. Vaccine production is a capital-intensive, fixed-costs-based business, with the average cost to bring a vaccine to market of about \$700 million. Moreover, the research, development, testing, and government approval process is very expensive, time-consuming, and risky. Several years and millions of dollars might be spent on developing a new vaccine only to find it fail in the final stages of testing, or to have the government refuse to approve it or significantly limit its application or distribution. Vaccine manufacturers will therefore invest in developing a new vaccine only where they see both a need for the vaccine as an improvement over an existing vaccine and an opportunity to make a large enough return on the significant capital investment and risk involved.

31. In the case of the U.S. Market for Mumps Vaccine, this substantial and inherent barrier to entry is compounded by the falsely inflated efficacy rate of Merck’s vaccine. As with the market for any product, a potential competitor’s decision to enter a market hinges on whether its product can compete with those products already being sold in the market. If an existing

vaccine is represented as safe and at least 95 percent effective, as Merck has falsely represented its vaccine to be, it would be economically irrational for a potential competitor to bring a new Mumps Vaccine to the Relevant Market unless it thought it could compete with the safety and efficacy of the existing vaccine. Health care providers, including Plaintiffs and the Class, would not purchase it otherwise.

(d) There Is High Inelasticity Of Demand In The Mumps Vaccine Market

32. For those seeking immunization for mumps, Mumps Vaccine is the only product available to achieve that result. So regardless of the price Merck charges for its Mumps Vaccine, the extent or frequency of any price increases for the vaccine, or whether Merck incorporates the vaccine into multi-disease vaccines, as it does with M-M-R®II and ProQuad®, there are no alternative products to which the government, health care professionals, or consumers can turn to obtain this immunization.

33. The U.S. Market for Mumps Vaccine is further defined by the CDC's nationwide schedule of recommended childhood vaccinations, including a vaccination against mumps, and the requirement around the country that all public school students be vaccinated against mumps (among other childhood diseases). If a child is to attend public school – not to mention any private school, university, summer camp, or other educational or recreational institution in this country – he or she must be vaccinated for mumps. There is no choice (but for rare exceptions). There is no alternative. No other products can substitute for this required vaccination.

B. Merck Willfully Maintained And Unlawfully Enhanced Its Monopoly Power In The Mumps Vaccine Market Through A Decade-Long Fraud

34. To obtain its original government approval to sell its Mumps Vaccine, Merck conducted field studies of vaccinated children and concluded that the vaccine had an efficacy

rate of 95 percent or higher.¹ This meant that 95 percent of those given the vaccine were considered immunized against mumps. This is important because when an adequate number of people have immunity, the chances of an outbreak are reduced, and – ultimately – eliminated, even for people who are not vaccinated or are improperly vaccinated. This is what is known as “herd immunity.” If there is insufficient immunity, a real risk of continued disease outbreaks exists. When a mumps outbreak occurs in vaccinated populations, it typically afflicts adults and older children who are at greater risk of serious complications.

35. While Merck obtained its original license in 1967, stating that its vaccine was at least 95 percent effective, Merck had known and knows that the vaccine’s efficacy is significantly less than that now. Merck knows that the continued passaging of the attenuated virus to make more vaccine for distribution has altered the virus and has degraded the efficacy of the product.

36. Rather than develop a new Mumps Vaccine with greater efficacy, or prompt the development of competing vaccines by disclosing the true efficacy of its product, Merck has instead taken pains to unlawfully and unethically preserve its exclusive U.S. license by maintaining that its more than forty-year old vaccine continues to have an efficacy rate of 95 percent or higher. This was easy to do for a while because Merck was able to rely on the efficacy testing it conducted in connection with the government’s original granting of Merck’s license to sell Mumps Vaccine. However, beginning in the late 1990s, Merck’s application to change the M-M-R®II labeling in the U.S. and an application for a license to sell M-M-R®II in Europe required new efficacy testing of its Mumps Vaccine. This testing also coincided with Merck’s development and quest for approval of ProQuad® in both the U.S. and Europe.

¹ See Maurice R. Hillman et al., *Live, Attenuated Mumps Virus Vaccine 4. Protective Efficacy as Measured in a Field Evaluation*, 276 N. ENGL. J. MED. 252, 255-57 (Feb. 2, 1967).

37. If Merck failed to demonstrate that its Mumps Vaccine was still 95 percent effective, it risked losing the monopoly it had over the sale of Mumps Vaccine in the U.S. With respect to M-M-R®II or Mumpsvax®, additional competition would have driven down the price of the vaccines. Plaintiffs and members of the Class would either have obtained a better price for the vaccine or stopped purchasing the vaccine from Merck altogether. With respect to ProQuad®, the government might not have approved the vaccine at all for sale in the U.S. Under any of these scenarios, Merck risked losing hundreds of millions of dollars in revenue from this very profitable but unlawful monopoly.

38. Because of this, Merck set out to conduct testing of its Mumps Vaccine that would support its original efficacy finding. In performing this testing, Merck was determined to report a seroconversion rate of 95 percent or higher regardless of the vaccine's true efficacy. As it turned out, the only way Merck could accomplish these results was through manipulating its testing procedures and falsifying the test results. Relators to the *Qui Tam* Action participated on the Merck team that conducted this testing and witnessed firsthand the fraud to which Merck resorted to obtain its desired results. Merck internally referred to the testing as Protocol 007.

1. Merck Manipulated And Falsified Test Results To Distort The True Efficacy Of Its Mumps Vaccine

(a) Merck's Abandonment Of Its Original PRN Test And Test Results

39. The original methodology Merck employed under Protocol 007 was a Mumps Plaque Reduction Neutralization (“PRN”) Assay. Preliminary testing commenced in 1999 at Merck’s West Point facility and was led by Senior Investigator David Krah and his second-in-command, Mary Yagodich. Merck’s Executive Director of Vaccine Research, Alan Shaw, approved the testing methodology Krah and Yagodich employed. Relator Krahling witnessed Krah and Yagodich as they conducted the preliminary testing.

40. As the name of the test indicates, the PRN test measures the virus neutralization that occurs after administration of the Mumps Vaccine. Merck's first test was in some measure similar to the testing procedure regarded in the scientific community as the "gold standard" for testing how well a vaccine works. Blood samples are taken from children both before they receive the vaccine and again after they have been injected with the vaccine (after sufficient time has passed for the vaccine to produce an immune response). The paired blood samples are then individually incubated with the target virus and added to sheets of cells. Where the virus replicates in the cell sheet it leaves a plaque or hole.

41. The pre-vaccinated child will not typically have immunity to the disease. Therefore, the pre-vaccinated blood will be unable to neutralize the virus and plaques will form where the virus has infected the cells. In contrast, if the vaccine has stimulated the child's immune system to develop antibodies against the virus, the post-vaccinated blood will neutralize the virus. The post-vaccinated blood sample will consequently show a smaller number of plaques, or holes, in the cell sheet compared to the pre-vaccinated sample.

42. A PRN test simply compares virus growth in the presence of the pre- and post-vaccinated blood samples. The number of plaques (where the virus has grown) is compared to determine if the vaccine caused the child to develop a sufficient level of antibodies to neutralize the virus. Results are reported in terms of seroconversion. A seroconversion occurs when the pre-vaccination blood sample is "negative" (meaning insufficient antibodies to neutralize the virus) and the post-vaccination sample is "positive" (meaning sufficient antibodies to neutralize the virus). Seroconversion occurs, therefore, when a blood sample goes from "pre-negative" (insufficient antibodies) to "post-positive" (sufficient antibodies). In the lab, seroconversion is the best correlate for efficacy – how successful the vaccine is at immunizing children. For the

purposes of its testing, Merck was looking for a seroconversion rate of 95 percent or higher to support its original efficacy finding and the efficacy it continued to represent in its labeling.

43. While Merck's PRN test was modeled after the neutralizing test generally accepted in the industry, it diverged from this "gold standard" test in a significant way. It did *not* test the vaccine for its ability to protect against a wild-type mumps virus. A wild-type virus is a disease-causing virus. That is the type of real-life virus against which vaccines are generally tested. Instead, Merck tested the children's blood for its capacity to neutralize the attenuated Jeryl Lynn strain of the virus. This was the same mumps strain with which the children were vaccinated. The use of the attenuated Jeryl Lynn strain, as opposed to a virulent wild-type strain, subverted the fundamental purpose of the PRN test, which was to measure the vaccine's ability to provide protection against a disease-causing mumps virus that a child would actually face in real life. The end result of this deviation from the accepted PRN gold standard test was that Merck's test overstated the vaccine's effectiveness.

44. Even with a deviation that could only overstate how well the vaccine worked, the results from Merck's preliminary testing (which involved testing blood samples of approximately 60-100 children) yielded seroconversion rates significantly below the desired 95 percent threshold. Krah admitted as much to Relator Krahling. He also admitted to Krahling that the efficacy of Merck's vaccine had declined over time, explaining that the constant passaging of virus to make more vaccine for distribution had degraded the product and that because of this, mumps outbreaks would increase over time.

45. Krah further admitted to Krahling that he and Yagodich tried numerous other, often undocumented, techniques to modify the PRN test to improve the seroconversion results they could measure, including trying different virus dilutions, different staining procedures and

even counting plaques more liberally. These other techniques – like using the vaccine strain rather than a wild-type strain of the virus – subverted the purpose of the PRN test. In the end, however, none of it mattered. Merck had to abandon its methodology because no matter how Krah and Yagodich manipulated the procedures, they could not reach the 95 percent seroconversion threshold.

46. To reach this threshold, Merck abandoned the PRN methodology that yielded unsatisfactory results and worked towards developing a new, rigged methodology that would allow Merck to report its desired seroconversion results.

(b) Back To The Drawing Board: Merck's Improper Use Of Animal Antibodies In Its "Enhanced" PRN Test

47. The new methodology Merck devised and ultimately used to perform the mumps efficacy testing under Protocol 007 was an “enhanced” PRN Assay. It was again led by Krah and approved by Shaw and commenced in 2000. Relators Krahling and Wlochowski participated on the team that conducted the testing using this supposedly enhanced methodology. Each of them witnessed firsthand the falsification of the test data in which Merck engaged to reach its 95 percent seroconversion threshold. In fact, each was significantly pressured by Krah and other senior Merck personnel to participate in this fraud.

48. From the outset, Merck’s objective with this “enhanced” procedure was clear. It was not to measure the actual seroconversion rate of Merck’s Mumps Vaccine. Rather, it was to come up with a methodology that would yield a minimum 95 percent seroconversion rate regardless of the vaccine’s true efficacy. The very first page of an October 2000 Merck presentation on the “enhanced” methodology stated just that:

Objective: Identify a mumps neutralization assay format . . . that permits measurement of a \geq 95% seroconversion rate in M-M-R®II vaccines.

Notably, nowhere in this presentation did Merck provide any kind of justification or explanation for abandoning its original PRN methodology and the unsatisfactory seroconversion results it yielded.

49. To reach the stated objective for its “enhanced” test and increase the measured seroconversion rate to the predetermined 95 percent threshold, Merck continued to use its scientifically flawed PRN methodology – that tested against the vaccine strain rather than a wild-type strain – but with one additional material change. Merck added animal antibodies to both the pre- and post-vaccination blood samples. The use of animal antibodies in laboratory testing is not uncommon. They can serve as a highlighter of sorts to identify and count human antibodies that otherwise might not be identifiable on their own. When used in that way, animal antibodies make it easier to see the human antibodies. They do not alter what is being measured. However, Merck added animal antibodies for the singular purpose of altering the outcome of the test by boosting the amount of virus neutralization counted in the lab.

50. In a laboratory setting, animal antibodies can combine with human antibodies to cause virus neutralization that would not otherwise occur from the human antibodies alone. Merck’s “enhanced” methodology permitted various types of human antibodies to be counted as mumps neutralizing antibodies when it was actually the animal antibodies combining with those human antibodies causing the neutralization. Merck also did not apply a proper “control” to isolate whether virus neutralization was caused by the human antibodies alone or in combination with the animal antibodies. Rather, Merck included in its seroconversion measure all virus neutralizations regardless of whether they resulted from human antibodies or by their combination with the animal antibodies. This “enhanced” PRN methodology thereby allowed

Merck to increase dramatically the recordable instances of mumps virus neutralization and to count those neutralizations toward seroconversion and its measure of the vaccine's success.

51. Merck knew that the neutralizations attributable to the animal antibodies would never exist in the real world. This is because the human immune system, even with the immunity boost provided by an effective vaccine, could never produce animal antibodies. And adding this external factor as a supplement to a vaccine was not an option because it could result in serious complications to a human, even death. Thus, the "uncontrolled" boost to neutralization Merck designed using these animal antibodies in its laboratory did not in any way correspond to, correlate with, or represent real-life (*in vivo*) virus neutralization in vaccinated people.

52. But the use of the animal antibodies allowed Merck to achieve its high seroconversion objectives. In fact, paired blood samples that were found under Merck's 1999 PRN methodology to lack sufficient virus neutralizing antibodies were now considered seroconverted using the "enhanced" methodology. Indeed, in one panel of 60 paired blood samples, Merck measured a seroconversion rate of 100 percent. In other words, non-neutralizing concentrations of antibodies that would never protect a child from mumps in the real world were, under Merck's "enhanced" methodology, treated as vaccine successful solely because of the additional neutralization provided by the animal antibodies.

53. Krah defended the use of the animal antibodies in the "enhanced" PRN test by pointing to the FDA's purported approval of the process. However, whatever FDA approval Merck may have received for this testing, there is no indication that the FDA was fully aware of the extent of Merck's manipulation of the testing, including Merck's wholesale fabrication of test data to reach its preordained 95 percent efficacy threshold.

(c) Back To The Drawing Board Again: Merck's Falsification Of The "Enhanced" PRN Test Results

54. There was a significant problem with Merck's improper use of the animal antibodies to boost its virus neutralization counts which would be evident to any scientist reviewing the test data. The animal antibodies boosted neutralization counts not only in the post-vaccination blood samples, but also in the pre-vaccination samples. However, too much virus neutralization in the pre-vaccinated sample created a "pre-positive," which means enough virus neutralization to characterize the child as immune without the vaccine.

55. Pre-positives ordinarily occur in a small percentage of the child population that is immune to mumps even without vaccination. This immunity would principally come from a previous exposure to the mumps virus, or from immunity transferred to a child from the mother *in utero*. However, the incidence of this immunity is small, generally measured by the scientific community at around 10 percent of the child population.

56. The problem for Merck was that, with the addition of the animal antibodies to the pre-vaccination blood samples, it was seeing a significantly higher percentage of pre-positives than the 10 percent industry recognized occurrence of such immunity. In the results of one test that Relators Krahling and Wlochowski both witnessed in the Summer of 2001, the pre-positive rate was more than 80 percent. Krah instructed Wlochowski to throw out the results and the actual experimental plates of that particular test, thereby destroying all traces of the unwanted results.

57. The existence of such a high percentage of pre-positives threatened the viability of Merck's "enhanced" methodology. As a practical matter, with a pre-positive, any favorable results in the post-vaccinated sample could not be counted as a vaccine success toward the 95

percent seroconversion target. A sample appearing positive before the vaccine, and staying positive after the vaccine, was not a seroconversion.

58. Just as important, the high pre-positive rate would red flag the methodology as flawed. The FDA would question the results of a test that had such a high level of pre-positives. Krah stated this explicitly to the members of his lab, including Relators Krahling and Wlochowski. If Merck wanted to keep the artificial boost in post-vaccination positives provided by the animal antibodies, it would have to eliminate the associated boost in pre-vaccination positives.

59. In the October 2000 presentation, Merck acknowledged that its initial “enhanced” PRN testing results yielded a level of pre-positives that was too high. Merck also made clear that it needed to “optimize” the amount of animal antibodies used in the process so that the testing would yield a pre-positive rate of 10 percent or less and a seroconversion rate of 95 percent or more: “Pre-positive rate is higher than desirable,” and “Continue evaluation of results using optimized [animal antibodies] amount (target \leq 10% pre-positive rate and \geq 95% seroconversions).”

60. The problem was that no matter how it was tinkered, no amount of animal antibodies added would produce a pre- and post-vaccination virus neutralization for Merck’s vaccine within the desired range. Without the animal antibodies, Merck could not support a sufficient level of post-vaccination neutralization. Conversely, by adding the animal antibodies, Merck could not avoid having too high a level of pre-vaccination neutralization (*i.e.*, too many pre-positives). This left only one way for Merck to reach its desired seroconversion outcome – falsify the test results.

61. Specifically, Krah and Yagodich and other members of Krah's staff falsified the test results to ensure a pre-positive neutralization rate of below 10 percent. They did this by fabricating their plaque counts on the pre-vaccination blood samples, essentially counting plaques that were not actually there. With these inflated plaque counts, Merck was able to count as pre-negative those blood samples that otherwise would have been counted as pre-positive because of the increased neutralization caused by the animal antibodies.

62. Merck's falsification of the pre-vaccination plaque counts was performed in a broad-based and systematic manner from December 2000 until at least August 2001:

- Krah stressed to his staff that the high number of pre-positives they were finding was a problem that needed to be fixed.
- Krah directed his staff to re-check any sample found to be pre-positive to see if more plaques could be found to convert the sample to a pre-negative.
- Krah and Yagodich falsified plaque counts to convert pre-positives to pre-negatives, and directed other staff scientists to do the same.
- Krah appointed Yagodich and two others to "audit" the testing that other staff scientists had performed. These audits were limited to finding additional plaques on pre-positive samples thereby rendering them pre-negatives.
- Krah instituted several measures to isolate the pre-positive samples, to facilitate their "re-count," and to convert them to pre-negatives. For example, when manually changing original counting sheets proved too time-consuming, Krah employed an Excel spreadsheet which would automatically highlight the undesirable pre-positives so that they could be targeted more efficiently. The data was entered, highlighted and changed before it was ever saved.
- Krah also engaged in the destruction of evidence to minimize the chances of detection. He not only used an Excel spreadsheet to avoid a paper trail, he also destroyed test results, substituted original counting sheets with "clean" sheets, and ordered the staff in the lab to do the same.
- Merck cancelled (in March 2001) a planned outsource of the testing to a lab in Ohio because the outside lab was unable to replicate the seroconversion results Krah was obtaining in his lab. Krah and his staff conducted all the remaining testing instead.

63. Unsurprisingly, none of the “recounting” and “retesting” that Krah and his staff performed as part of the “enhanced” testing was performed on any post-vaccination samples or on any pre-vaccination samples that were pre-negative. This additional “rigor” was only applied to the pre-positive samples, the very samples Merck had identified as undesirable and which kept Merck from attaining its target of $\leq 10\%$ pre-positive rate and $\geq 95\%$ seroconversion.

64. Relators Krahling and Wlochowski engaged in numerous efforts to stop the fraud. They questioned and complained to Krah about the methodology being employed, particularly the manipulation of pre-positive data. They attempted to dissuade others from participating. They initiated numerous telephone calls to the FDA to expose the fraud. They attempted to document the fraud, even as evidence of it was being destroyed. But Relators’ efforts were to no avail. For every effort they took to stop the fraud, Merck adapted the scheme to assure the falsification continued. For example, when Relators objected to changing their own plaque counts, Krah appointed other staff, as so-called auditors, willing to falsify the data.

65. In July 2001, Relators Krahling and Wlochowski secretly conducted their own audit of the test results to confirm statistically the fraud that was occurring with the “enhanced” testing. They reviewed approximately 20 percent of the data that Merck had collected as part of the “enhanced” test. In this sampling, they found that 45 percent of the pre-positive data had been altered to make it pre-negative. No pre-negatives were changed to pre-positives. No post-positives were changed to post-negatives. No post-negatives were changed to post-positives. The statistical probability of so many changes occurring in just the pre-positive data and in no other data was more than a trillion to one. And that is a conservative measure given the likelihood that an even greater number of pre-positives were changed but remained undetected because the changes were not recorded in Merck’s files.

(d) The Complicity Of Merck's Senior Management

66. Krah did not act alone in orchestrating the falsification of the "enhanced" PRN test results. He acted with the knowledge, authority, and approval of Merck's senior management.

67. For example, in April 2001, after Merck cancelled the planned outsourcing of the remainder of the Mumps Vaccine efficacy testing, Emilio Emini, the Vice President of Merck's Vaccine Research Division, held a meeting with Krah and his staff, including Relators Krahling and Wlochowski. Emini was clearly on notice of protests that had been going on in the lab because he directed Krah's staff to follow Krah's orders to ensure the "enhanced" testing would be successful. He also told the staff that they had earned very large bonuses for the work they had completed on the project so far. He was going to double the bonuses and pay them once the testing was complete.

68. In July 2001, after completing the secret audit, Relator Wlochowski openly accused Krah during a lab meeting of committing fraud in the Mumps Vaccine testing. Relator Krahling then met with Alan Shaw and confronted him about the fraudulent testing. Krahling told Shaw of the falsification of the pre-positive data. Krahling also confronted Shaw about the improper use of the animal antibodies to inflate the post-vaccine neutralization counts. Shaw responded that the FDA permitted the use of the animal antibodies and that should be good enough for Krahling. Shaw refused to discuss anything further about the matter. Instead, Shaw talked about the significant bonuses that Emini had promised to pay the staff in Krah's lab once the testing was complete.

69. Relator Krahling then met with Bob Suter, Krahling's human resources representative at Merck. Krahling told Suter about the falsification of data and Shaw's refusal to get involved. Krahling told Suter that he was going to report the activity to the FDA. Suter told

him he would go to jail if he contacted the FDA and offered to set up a private meeting with Emini where Krahling could discuss his concerns.

70. Shortly thereafter, Emini agreed to meet with Krahling. In an early August 2001 meeting with Emini, Krahling brought actual testing samples and plaque counting sheets to demonstrate to Emini the fraudulent testing that Krah was directing. Emini agreed that Krah had falsified the data. Krahling also protested against the use of the animal antibodies to inflate the seroconversion rate. Emini responded that the animal antibodies were necessary for Merck to achieve the project's objective. Krahling proposed a scientific solution to lower the pre-positive rate and end the need to falsify data – stop using the animal antibodies. When Emini declined, Krahling asked him what scientific rationale justified using the animal antibodies. Emini explained that Merck's choice to use the antibodies was a “business decision.”

71. To assuage Krahling's concerns, Emini promised to conduct an “internal audit” of the Mumps Vaccine testing. Krahling countered that the FDA should be contacted because only the FDA could perform an audit that was truly independent. Emini ordered Krahling not to call the FDA. Immediately after the meeting, Suter approached Krahling and again threatened that he would be put in jail if he contacted the FDA.

72. The next morning, Krah arrived early to the lab and packed up and destroyed evidence of the ongoing Mumps Vaccine testing. This evidence included garbage bags full of the completed experimental plates, containing the cell sheets with plaques, that would have (and should have) been maintained for review until the testing was complete and final. The destruction of the plates would make it difficult to compare the actual plaque counts in the test with what was documented and changed on the counting sheets, as Krahling had done the day

before in Emini's office. Despite the threats he received from Suter and Emini, Krahling called the FDA again and reported this latest activity in Merck's ongoing fraud.

(e) The FDA Interview Of Krah And Shaw

73. On August 6, 2001, in response to Relator Krahling's complaint, an FDA agent came to Merck to question Krah and Shaw. The FDA agent's questions were largely focused on Merck's process for counting plaques in the "enhanced" PRN test. Krah and Shaw misrepresented the process that Merck was actually conducting and the fact that Merck was falsifying the pre-positive test data.

74. For example, the FDA agent asked whether there was any *ad hoc* revisiting of plaque counts. Krah falsely responded that plaque counts were being rechecked only for verification, controls, and to check hypervariability. Krah also misrepresented to the FDA that they did not change the data after it was entered in the excel workbook. When the FDA agent pressed Krah on the criteria for changing original counts on the counting sheets, Krah left the interview without answering the question. In Krah's absence, Shaw informed the FDA agent that a memo would be added to the standard operating procedure to address changes. The FDA agent then asked Shaw why they had not taken care of this before the project started. Shaw offered that Krah and another Merck employee had identified "trends" and "problems" with the original counts without ever explaining what those "trends" or "problems" actually were.

75. The interview proceeded in this manner with Shaw and Krah (when present in the room) obfuscating what was happening in the lab and obstructing the FDA's efforts to find out what was really going on with Merck's manipulation of the testing procedure to reach its targeted seroconversion rate.

76. The entire FDA interview with Krah and Shaw was short, probably less than half an hour. The FDA agent did not question Relators Krahling or Wlochowski or other members of

Krah's staff in order to corroborate what Krah and Shaw said. As far as Relators witnessed, the FDA agent did not attempt to substantiate Krah's or Shaw's responses by reviewing any of the testing samples or backup data that had escaped destruction. And the FDA agent did not address the actual destruction of evidence that Krah had already facilitated.

77. The FDA issued a one-page deficiency report identifying a few relatively minor shortcomings in Merck's testing process. These principally related to flaws in Merck's record-keeping and in its validation/explanation of changes to the test data.

78. The report did not address or censure Merck for any issues relating to Merck's improper use of the animal antibodies or Merck's wide-scale falsification of pre-positive test data. The FDA did not discover this fraudulent activity in the course of the perfunctory visit because of Krah and Shaw's misrepresentations to the FDA.

(f) Merck's Completion And Use Of The Fraudulent Test Results

79. In order to comply with the FDA's deficiency report, Merck made minor adjustments to its testing procedure relating to its heretofore *ad hoc* procedure for counting plaques. The new, more formalized procedure explicitly provided for supervisory oversight and review of plaque counts in pre-vaccinated blood samples and where plaques were difficult to read because of the condition of the sample. In other words, under the "new" procedure, Merck continued to falsify the test data to minimize the level of pre-positives and inflate the seroconversion rate.

80. After the FDA visit, Relator Krahling was barred from any further participation in the Protocol 007 Mumps Vaccine testing project. He was also prohibited from accessing any data related to the project. Shortly thereafter, he was given a poor performance review and barred from continuing to work in Krah's lab on any matter. He was offered a position in a

different lab within Merck's vaccine division, but it involved work for which Krahling had no prior experience or interest. In December 2001, Krahling resigned from the Company.

81. Relator Wlochowski continued to work at Merck, though she was transferred out of Krah's lab at the end of September 2001. She spent an additional year working at Merck in a different lab before she too left Merck.

82. Before Relators Krahling and Wlochowski left Krah's lab, Merck conducted the internal audit Emini had promised Relator Krahling would take place. However, as Krahling had warned against, the audit was anything but independent. Unsurprisingly, therefore, Merck completed its Protocol 007 testing in late Summer or early Fall 2001 and Merck reported the 95 percent seroconversion it had targeted from the outset.

2. Merck Fraudulently And Deceptively Marketed Its Mumps Vaccine For Over A Decade

83. Since at least the beginning of the Protocol 007 testing and continuing through the present, Merck has falsely represented to the government and the public (and thus, effectively, to its competitors) that its Mumps Vaccine has at least a 95 percent efficacy rate. It has done so even though Merck is well aware, and has taken active steps to conceal, that the efficacy rate is far lower.

(a) Merck's False Representations And Omissions Through Package Inserts And Marketing

84. Merck has made false representations in the package insert or labeling that accompanies each dose of Merck's Mumps Vaccine. This is the product material that the law requires which, among other things, informs health care providers and the public of the composition of the vaccine and its overall efficacy at immunizing the recipient from contracting mumps.

85. Merck's Mumps Vaccine insert has changed over the years, but at least one thing has remained constant -- Merck's reporting of at least a 95 percent efficacy rate. The current package insert for M-M-R®II provides that "a single injection of the vaccine induced . . . mumps neutralizing antibodies in 96% . . . of susceptible persons." Merck neither identifies the study performed or the date it was performed that supposedly supports this representation. The current insert further provides: "Efficacy of measles, mumps and rubella vaccines was established in a series of double-blind controlled field trials which demonstrated a high degree of protective efficacy afforded by the individual vaccine components." As support for this representation, Merck cites the more than 40-year old studies it conducted to obtain the original governmental approval for its Mumps Vaccine in 1967. Merck's M-M-R®II package insert has contained this language and "support" since at least 1999. Those inserts omit any information about the declining efficacy of the vaccine that became apparent during the Protocol 007 testing.

86. Merck's package insert is a clear misrepresentation of the efficacy rate of its Mumps Vaccine and otherwise omits material information that contradicts reported efficacy rates. It cites outdated or unidentified studies that are not reflective of what Merck knows now about the vaccine's current effectiveness as confirmed by Merck's efforts to manipulate the methodology and ultimately falsify the data to report at least 95 percent seroconversion. In short, as Merck well knows, the efficacy rate of its Mumps Vaccine is not anywhere near 95 percent. Yet Merck continues to falsely represent a 95 percent efficacy rate to ensure its continued monopoly on the sale of the vaccine in the U.S.

(b) Merck's False Representations And Omissions Through Expanded Distribution of the Vaccine

87. Merck's misrepresentations and omissions relating to its Mumps Vaccine have not been made just for M-M-R®II. Merck has also obtained approval to sell M-M-R®II in

Europe and to sell ProQuad® in the U.S. and Europe by misrepresenting to the FDA (in the U.S.) and the EMA (in Europe) the efficacy rate of its Mumps Vaccine and omitting the true results of its recent efficacy testing.

88. In 2004, Merck submitted an application to the FDA for approval of ProQuad®. Merck certified the contents of its application were true. In 2005, after reviewing Merck's application, the FDA approved ProQuad®. According to the FDA's clinical review of the studies Merck submitted in support of ProQuad®, “[c]linical efficacy of ... mumps ... vaccine strain w[as] shown previously ... using [the] monovalent. [T]he vaccine response rates were 95.8 to 98.8% for mumps.” Merck knew from its Protocol 007 testing that this falsely represented the efficacy of its Mumps Vaccine, but omitted this information from its applications. Now that it is licensed, Merck's package insert continues to misrepresent the efficacy of its Mumps Vaccine, stating: “Clinical studies with a single dose of ProQuad® have shown that vaccination elicited rates of antibody responses against measles, mumps, and rubella that were similar to those observed after vaccination with a single dose of M-M-R II” and “[a]ntibody was detected in 96.7% for mumps.”

89. In 2006, Merck obtained a license from the EMA to sell the M-M-R®II analogue (called M-M-RVaxpro®) through the joint venture Sanofi Pasteur MSD. Merck again used the falsified results of the “enhanced” PRN test to obtain this approval. The EMA actually cited Protocol 007 as a “pivotal clinical study” in support of its decision to grant the approval. Since then, Merck has been manufacturing M-M-RVaxpro® at its West Point facility for Sanofi Pasteur MSD to sell in Europe.

90. Around the same time, Merck also obtained a license from the EMA for Sanofi Pasteur MSD to sell Merck's ProQuad® in Europe. As with M-M-RVaxpro®, Merck's joint

venture submitted the falsified results of Protocol 007 to the EMA as supportive clinical information in its vaccine application. Relying on this information, the EMA found “no major concern” about the efficacy of the mumps component of the vaccine.

91. Thus, by 2006, Merck had the exclusive licenses to sell M-M-R®II and ProQuad® in the U.S., as well as licenses to sell M-M-RVaxpro® and ProQuad® in Europe.

(c) Merck’s False Representations And Omissions Through Its Application For A Labeling Change On The Potency Of M-M-R®II

92. In 2007, Merck changed its M-M-R®II labeling to reflect a decrease in the potency of the mumps component of the vaccine. Potency measures how much of the attenuated virus is included in each dose of the vaccine. The labeling change – approved by the FDA – allowed Merck to represent a lower minimum potency, from 20,000 to 12,500 TCID₅₀ (or tissue culture infective dose, which is the scientific measure of vaccine potency). This represented a 37.5 percent reduction in how much of the attenuated virus could go into each dose of the vaccine.

93. At no time during Merck’s efforts to secure approval to change its M-M-R®II labeling did Merck disclose to the FDA what Merck knew about the diminished efficacy of the vaccine. Nor did Merck take any steps to address the efficacy information that was falsely represented in the labeling. That portion of the labeling remained unchanged.

94. Merck was thus representing throughout the approval process that it could actually *reduce* how much attenuated virus Merck put into each vaccine shot and still maintain its represented 95 percent efficacy. Merck did so even though it knew that at the *higher* potency the vaccine was nowhere near the 95 percent efficacy.

(d) Merck's False Representations And Omissions Through Recent Mumps Outbreaks

95. With Merck's significantly degraded vaccine as the only protection against the mumps in this country, there has remained a significant risk of a resurgence of mumps outbreaks. That is exactly what Krah – who was well aware of the Mumps Vaccine's failings – predicted would occur. In a conversation he had with Relator Krahling in the midst of the “enhanced” PRN testing, Krah acknowledged that the efficacy of Merck’s vaccine had declined over time, explaining that the constant passaging of virus to make more vaccine for distribution had degraded the product. Krah predicted that because of this, mumps outbreaks would continue. The predictions came true – that is exactly what has happened.

(i) The 2006 Mumps Outbreak

96. In 2006, more than 6,500 cases of mumps were reported in the Midwest in a highly vaccinated population. This was the largest mumps outbreak in almost 20 years and a significant spike from the annual average of 265 cases that had been reported for the years leading up to the 2006 outbreak. Astoundingly, 84 percent of the young adults who contracted the disease had been vaccinated with two doses of the Mumps Vaccine.

97. Experts on infectious diseases struggled to understand the origins of the outbreak despite the two-dose vaccination in much of the affected population.

98. According to an ABC News article published during the outbreak: “It’s not known precisely why this mumps outbreak is occurring, especially when so many U.S. residents receive a vaccination for it during childhood. Infectious disease expert Dr. William Schaffner said he hopes that the Centers for Disease Control and Prevention will fully investigate why Americans are coming down with the illness.” *Mumps Outbreak Swells Across Midwest*,

AbcNews.com, Apr. 7, 2006, <http://abcnews.go.com/Health/story?id=1817842&page=1>.

99. The Associated Press likewise noted that “[m]ost of the college students who got the mumps in a big outbreak in 2006 had received the recommended two vaccine shots” and that this “‘two-dose vaccine failure’ startled public health experts, who hadn’t expected immunity to wane so soon—if at all.” Linda A. Johnson, *Mumps Outbreak Stirs Vaccine Questions*, Associated Press, Apr. 10, 2008, available at http://seattletimes.nwsource.com/html/health/2004338902_mumps10.html.

100. The CDC, FDA, and Merck publicly worked together to determine the cause of this 2006 outbreak. Of course, only Merck knew that outbreaks would occur because its vaccine had degraded over time and was weaker than what Merck represented. Nonetheless, Merck continued to represent its inflated efficacy rate while government and private health care providers continued to believe that there was no problem with the vaccine. During the investigation of the outbreak, the CDC’s then Director, Julie Gerberding, reaffirmed the CDC’s view that nothing was wrong with the Mumps Vaccine, a belief fed by Merck’s continued misrepresentations: “*We have absolutely no information to suggest that there is any problem with the vaccine.*” Director Gerberding and the CDC emphasized that “[t]he best protection against the mumps is the vaccine.”

101. Even though Krah, the Merck investigator who ran Protocol 007, expected outbreaks to increase because of the degraded product, scientists at the CDC and elsewhere continued researching to understand the origins of such a large outbreak within a highly vaccinated population. One of the leading studies was led by Dr. Gustavo Dayan, then a doctor at the CDC, and published in 2008 in the *New England Journal of Medicine*. After considering possible causes for the outbreak, Dr. Dayan recommended that “[f]uture studies will help evaluate national vaccine policy, including whether the administration of a second dose of M-M-

R vaccine at a later age or the administration of a third dose would provide a higher or a more durable immunity.” Gustavo H. Dayan et al., *Recent Resurgence of Mumps in the United States*, 358 N. ENG. J. MED. 1580 (Apr. 10, 2008).

102. Dr. Dayan’s study ultimately concluded that “[a] more effective Mumps Vaccine or changes in vaccine policy may be needed to avert outbreaks and achieve elimination of mumps.” *Id.* Of course, if Dr. Dayan had the benefit of what Merck knew but willfully withheld from the government and the public, his findings would have been significantly less equivocal on what needed to be done to stop the reemergence of mumps outbreaks.

103. At the same time Dr. Dayan published his study questioning whether it may be time for a new vaccine, Merck publicly proclaimed that its Mumps Vaccine had not been changed since its introduction in 1967 and that Merck had no plans to change it. While Dr. Dayan questioned whether it may be time for a new vaccine, Merck attempted to reassure the public that there was no need for any such change and the vaccine worked just fine.

104. In another study on the 2006 outbreak, several scientists questioned Merck’s use of the Jeryl Lynn strain, instead of a wild-type virus, in Merck’s PRN testing. They noted that with this kind of testing, vaccine efficacy can be significantly overstated because “good results can be obtained that do not reflect the actual ability of the vaccine to provide protection from disease. A vaccine failure is investigated properly only if, in addition to avidity testing, the ability of antibodies to neutralize wild mumps virus has been checked.” Heikki Peltola et al., *Mumps Outbreaks in Canada and the United States: Time for New Thinking on Mumps Vaccine*, 45 CLIN. INFECT. DIS. 459, 463 (Aug. 15, 2007).

105. What is perhaps most notable about this study is that it scientifically questioned Merck’s stated efficacy based solely on Merck’s use of the vaccine strain instead of a wild-type

virus to test efficacy. The critique did not (and could not) even account for Merck's concealed efforts to further inflate its efficacy results with the improper use of animal antibodies and the falsification of test data.

106. Currently, Emory University is conducting a clinical trial of its university students in yet another attempt to explain the cause for the 2006 mumps outbreak among college-age students who had received both doses of the vaccine. However, Merck is listed as a collaborator on that study and is providing funding, thus continuing to exert its influence to perpetuate its fraudulent efficacy findings.

107. Merck's ongoing misrepresentations and omissions with respect to the effectiveness of its vaccine continue to conceal the role its degraded product played in the 2006 outbreak.

(ii) The 2009 Mumps Outbreak

108. In his 2008 study, Dr. Dayan also predicted another mumps outbreak would follow three years after the 2006 outbreak. This prediction was premised on the three-year cycles in which outbreaks occurred before children were widely vaccinated for mumps. “[I]n the prevaccine era, mumps activity followed 3-year cycles, so the current low activity rate [at the time of his 2008 study] may be transient while another critical mass of susceptible persons accrues.” Dayan, 358 NEW ENG. J. MED. at 1587-88.

109. In August 2009, another mumps outbreak began just as Dr. Dayan predicted. As with the 2006 outbreak, the 2009 outbreak occurred despite high vaccination coverage among the U.S. children’s population. In total, roughly 5,000 cases were confirmed by the CDC during the 2009 outbreak. This outbreak reaffirmed Krah’s prediction that mumps outbreaks would reemerge and increase over time.

110. Because of the 2006 and 2009 outbreaks, the CDC has also pushed back its target date for eradicating mumps from its earlier 2010 goal to no earlier than 2020. But no amount of extra time or dosages will be enough to eliminate the disease when the vaccine does not work as represented.

C. The Anticompetitive Effects Of Merck's Unlawful Monopolization Of The Mumps Vaccine Market

111. Through its false representations and omissions regarding the Mumps Vaccine's efficacy rate and its efforts to conceal the significantly lower efficacy rate that the Protocol 007 testing confirmed, Merck has unlawfully monopolized the Relevant Market and foreclosed potential competitors from entering the Market with a new Mumps Vaccine. No manufacturer would rationally invest the time, energy, and resources necessary to developing a new vaccine for sale in the U.S. with the artificially high bar Merck has established through fraud and omission.

112. Entering the Relevant Market would be particularly risky in the case of the Mumps Vaccine given the four-decade lock Merck has had on the Market.

113. But for Merck's anticompetitive conduct, including its fraud and other misconduct, one or more competing manufacturers would have entered this lucrative Market – with its guaranteed sales of almost eight million doses a year – with a competing Mumps Vaccine. For example, GlaxoSmithKline, a manufacturer of numerous FDA approved vaccines, has an M-M-R vaccine, Priorix®, that is widely sold in Europe, Canada, Australia, and other markets. Priorix® is not licensed or sold in the U.S., even though the company has a U.S. patent covering the vaccine and, according to an industry journal, had plans to enter the U.S. market with it.

114. Moreover, if Merck had disclosed the true efficacy of its Mumps Vaccine, the National Institutes of Health (NIH) likely would have funded the development of a new vaccine long before the historic mumps outbreaks in 2006 and 2009.

115. Recently, the NIH has begun to recognize that the Mumps Vaccine is not as effective as Merck claims. After years of building its mumps-prevention strategy around Merck's Mumps Vaccine, the NIH concluded earlier this year that it is time to develop a new vaccine.

116. On May 12, 2012, the NIH awarded Dr. Biao He of the University of Georgia a grant to develop a new vaccine.

117. The NIH website provides a description of this project that explicitly designates Merck's Mumps Vaccine as "not effective." According to the website:

[e]ven with widespread vaccination programs in place, mumps outbreaks continue to occur. The largest [mumps] outbreak in the U.S. after implementation of two-dose [mumps] vaccination program occurred in 2006. It is considered the first failure of two-dose [mumps] vaccination. In 2010, a large [mumps] outbreak occurred in NY/NJ area The fact that outbreaks had occurred in populations with over 95% coverage of two-dose [mumps] vaccine **strongly suggests that the current vaccine is not effective**.

Project Information No. 1R01AI097368-01A1 *Developing a Novel Mumps Virus Vaccine*, NIH Research Portfolio Online Reporting Tools,
http://projectreporter.nih.gov/project_info_description.cfm?aid=8371494&icde=12549650&ddparam=&ddvalue=&ddsub=&cr=10&csb=default&cs=ASC. (emphasis added).

118. Moreover, the project description on the NIH website identifies the long-term goal of the project as "develop[ing] a new mumps vaccine with long-lasting immunity." And the "Public Health Relevance Statement" portion of the project description declares: "Recently, large outbreaks in vaccinated populations have occurred at increasing frequency. The outbreaks

of mumps virus . . . infection in vaccinated populations underscore the *urgency and importance of developing a new and effective vaccine* against mumps . . . ” *Id.*(emphasis added).

119. Prior to these recent actions, the NIH had not expressed any concern about the Mumps Vaccine and had not spent any money on researching a new vaccine in many years.

120. In reality, however, Merck knew long before the historic U.S. mumps outbreaks that its Mumps Vaccine was not as effective as represented. And if Merck had disclosed the true efficacy of its Mumps Vaccine, the NIH and other government agencies would have, instead of declaring a target date of 2010 for the total eradication of mumps, begun funding the development of a new vaccine well in advance of these outbreaks.

121. By continuing to monopolize the Relevant Market, by, *inter alia*, misrepresenting an artificially high efficacy rate, and engaging in the above-described misconduct, Merck has foreclosed competing manufacturers from entering the U.S. market. So long as Merck continues to monopolize the Relevant Market and engage in this misconduct, these manufacturers will continue to be excluded from the Relevant Market and Merck will unlawfully retain its unlawful monopoly with a vaccine that does not provide adequate immunization.

122. There are no legitimate pro-competitive efficiencies that justify Merck’s anticompetitive and/or otherwise unlawful conduct or outweigh its substantial anticompetitive effects.

123. Merck’s unlawful conduct has harmed competition by foreclosing other manufacturers from entering the Relevant Market. Without such competition, Merck has been able to unlawfully maintain and profit from its monopoly in this Market even though it is manufacturing and selling a sub-par vaccine. In the absence of this illegal market foreclosure, other manufacturers would have entered the Relevant Market with a higher quality and cheaper

vaccine. This competition, or the threat of such potential competition, would have forced Merck to respond by either selling its existing vaccine at a lower price or developing a better vaccine.

124. By unlawfully excluding and impairing competition, Merck's conduct has caused Plaintiffs and other Class members to pay more for Mumps Vaccine than they otherwise would have paid absent Merck's illegal, exclusionary conduct.

125. Given the absence of any competition in the Relevant Market, Merck has used its unlawful monopoly power to charge artificially inflated prices for its Mumps Vaccine. During the Class Period, Merck increased the prices it charged private health providers such as Plaintiffs for M-M-R®II vaccine by an astounding 85%. *See Figure 1.*

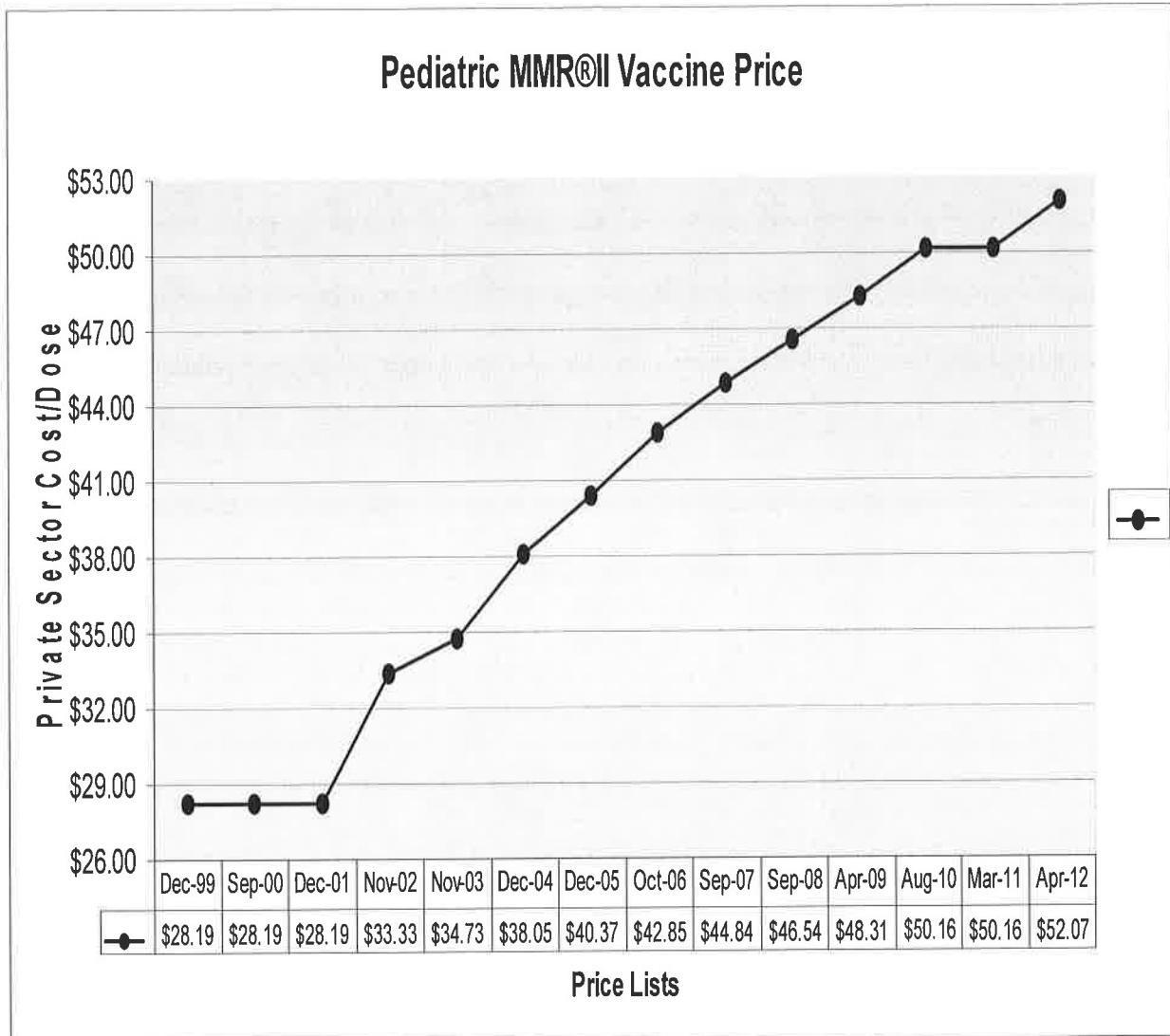


Figure 1.

126. As a result of Merck's unlawful, anticompetitive conduct, Plaintiffs and members of the Class were compelled to pay, and did pay, artificially high and supra-competitive prices for Mumps Vaccine.

127. Plaintiffs and members of the Class have, as a consequence, sustained losses and damage to their business and property in the form of the payment of overcharges for Mumps Vaccine. The full amount of such damages will be calculated after discovery and upon proof at trial.

CLASS ACTION ALLEGATIONS

128. Plaintiffs bring this class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(2) and (b)(3), on their own behalf and as representatives of the following class of persons and entities (the “Class”):

All persons or entities that purchased Mumps Vaccine directly from Defendant at any time between January 1, 1999 and the present (the “Class Period”). Excluded from the Class is Defendant and its subsidiaries, parents, or affiliates, whether or not named as a Defendant in this Consolidated Amended Complaint.

129. The State Consumer Protection Subclass consists of all members of the Class who reside in a state listed in ¶ 157.

130. The Class is individually so numerous that joinder of all members is impracticable. While the exact number of members of the Class is unknown to Plaintiffs at this time, based on the nature of the trade and commerce involved, Plaintiffs reasonably believe that there are at least thousands of members in the Class and that their identities can be identified from records in Merck’s possession, custody, or control.

131. Class members are geographically dispersed throughout the U.S.

132. Plaintiffs’ claims are typical of the claims of the other members of the Class.

133. Plaintiffs and the members of the Class have all sustained damage in that, during the Class Period, they purchased Mumps Vaccine directly from Merck at artificially maintained, supra-competitive prices, established by Merck’s actions in connection with the anticompetitive behavior alleged herein. Merck’s anticompetitive conduct, the effects of such violations, and the relief sought are all issues or questions that are common to Plaintiffs and the other Class members.

134. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class action and antitrust

litigation. Plaintiffs' interests are coincident with, and not antagonistic to, the interests of the other Class members.

135. Common questions of law and fact exist as to all members of the Class and predominate over any questions affecting solely individual members of the Class.

136. The questions of law and fact common to the Class include, but are not limited to:

- (a) whether the U.S. market for Mumps Vaccine constitutes a Relevant Market;
- (b) whether Merck possesses monopoly power in the Relevant Market;
- (c) whether, through the unlawful conduct alleged herein, Merck willfully acquired, maintained, or enhanced its monopoly power in the Relevant Market;
- (d) whether Merck monopolized the Relevant Market by engaging in unlawful exclusionary conduct to acquire, maintain, or enhance its monopoly power in the Relevant Market;
- (e) whether Merck misrepresented the efficacy of its Mumps Vaccine in violation of state consumer protection law;
- (f) whether Merck engaged in unlawful, unfair, misleading, or deceptive business acts or practices in the marketing and sale of its Mumps Vaccine;
- (g) whether Merck breached its contracts with Plaintiffs and members of the Class;
- (h) whether Merck misrepresented the characteristics, uses, benefits, or qualities of its Mumps Vaccine in the ordinary course of business;
- (i) whether Merck's Mumps Vaccine was merchantable at the time of sale;

- (j) whether Merck breached its express or implied warranties made to Plaintiffs and members of the Class;
- (k) whether, and to what extent, Merck's conduct caused Plaintiffs and the members of the Class to pay supra-competitive prices for Mumps Vaccine and, thereby, suffer antitrust injuries; and
- (l) whether Plaintiffs and Class members are entitled to damages and, if so, the appropriate measure of damages.

137. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all members of the Class is impracticable.

138. The prosecution of separate actions by individual members of the Class would impose heavy burdens upon the courts and the parties, and would create a risk of inconsistent or varying adjudications of the questions of law and fact common to the Class. A class action would achieve substantial economies of time, effort, and expense, and would assure uniformity of decision as to persons similarly situated without sacrificing procedural fairness. There will be no material difficulty in the management of this action as a class action on behalf of the Class.

PLAINTIFFS' CLAIMS ARE NOT BARRED BY THE STATUTE OF LIMITATIONS

A. The Statute Of Limitations Did Not Begin To Run Because Plaintiffs Did Not And Could Not Discover These Claims

139. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Consolidated Amended Complaint.

140. Plaintiffs and the members of the Class had no knowledge of facts sufficient to place them on inquiry notice of the claims set forth herein, until the unsealing of the *Qui Tam* Action on June 21, 2012.

141. Plaintiffs and the members of the Class had no means from which they could have discovered the facts described in this Consolidated Amended Complaint before the unsealing of the *Qui Tam* Action on June 21, 2012.

142. No information in the public domain was available to Plaintiffs and the members of the Class, prior to the unsealing of the *Qui Tam* Action on June 21, 2012, that revealed sufficient information to suggest that Merck had for over a decade, and continues to, unlawfully monopolize the Relevant Market by falsifying and misrepresenting the true efficacy of its Mumps Vaccine. Plaintiffs and the members of the Class had no means of obtaining any facts or information concerning the efficacy of Merck's Mumps Vaccine.

143. For these reasons, the statute of limitations as to Plaintiffs and Class members' claims did not begin to run, and has been tolled with respect to the claims that Plaintiffs and the members of the Class have alleged in this Consolidated Amended Complaint.

B. Fraudulent Concealment Tolled The Statute Of Limitations

144. In the alternative, application of the doctrine of fraudulent concealment tolled the statute of limitations on the claims asserted herein by Plaintiffs and the members of the Class. Plaintiffs and the members of the Class did not discover, and could not discover through the exercise of reasonable diligence, the existence of the unlawful, anticompetitive conduct and exclusionary tactics alleged herein until June 21, 2012 when the *Qui Tam* Action was unsealed.

145. Because Merck's unlawful actions were not made public until June 21, 2012, before that time, Plaintiffs and members of the Class were unaware of Merck's unlawful conduct, and they did not know before then that they were paying artificially inflated prices for Mumps Vaccine throughout the U.S. during the Class Period.

146. As set forth in great detail above, Merck took affirmative action to conceal its wrongdoing, including destroying test results, taking steps to ensure that fraudulent

manipulations to testing procedures and results would not be detected, providing financial inducements to employees to conduct the fraud in a secret manner, threatening relators with jail or other harm if they revealed details of Merck's fraud, and lying to FDA investigators that investigated Merck's practices.

147. Mumps Vaccine is not exempt from antitrust regulation, and thus, before June 21, 2012, Plaintiffs and the Members of the Class could not have reasonably considered the Relevant Market to be an anticompetitive market. Accordingly, a reasonable person under the circumstances would not have been alerted to begin to investigate the legitimacy of Merck's Mumps Vaccine prices before June 21, 2012.

148. Plaintiffs and the members of the Class could not have discovered the alleged monopolization at an earlier date by the exercise of reasonable diligence because of the deceptive practices and techniques of secrecy employed by Merck to avoid detection of, and fraudulently conceal, its anticompetitive conduct and exclusionary tactics.

149. Because the alleged unlawful, anticompetitive conduct and exclusionary tactics were affirmatively concealed by Merck, Plaintiffs and members of the Class had no knowledge of any facts or information that would have caused a reasonably diligent person to investigate whether Merck was engaging in such unlawful, anticompetitive conduct and exclusionary tactics until June 21, 2012, when the *Qui Tam* Action was unsealed.

150. As a result of Merck's fraudulent concealment, the running of any statute of limitations has been tolled with respect to any claims that Plaintiffs and the members of the Class have alleged in this Consolidated Amended Complaint.

FIRST CLAIM FOR RELIEF
Monopolization In Violation Of Section 2 Of The Sherman Act, 15 U.S.C. § 2
(On Behalf Of Plaintiffs And The Class)

151. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Consolidated Amended Complaint.

152. Merck acquired, willfully maintained, and unlawfully exercised monopoly power in the Relevant Market through the exclusionary, anticompetitive conduct set forth above, including, but not limited to: (i) falsifying data in order to represent, and then falsely representing that its Mumps Vaccine is 95 percent effective in package inserts, government applications, and during recent outbreaks; and (ii) actively concealing the true, substantially lower efficacy of its Mumps Vaccine by destroying evidence of falsified data, lying to an FDA representative, attempting to buy the silence and cooperation of its staff by offering financial incentives, and threatening one then-employee, relator Stephen Krahling, with jail if he reported the fraud to the FDA.

153. Merck has effectively excluded competition from the Relevant Market, unlawfully acquired and expanded its dominant market share in the Relevant Market, and profited from its anticompetitive conduct by maintaining prices at artificially high levels and by otherwise reaping the benefits of its illegally obtained and maintained monopoly power.

154. There is no legitimate business justification for Merck's anticompetitive actions and the conduct through which it acquired and maintained its monopoly power in the Relevant Market. The anticompetitive effects of Merck's conduct far outweigh any conceivable pro-competitive benefit or justification. Even if such justification had existed, any possible pro-competitive benefits could have been obtained by less restrictive alternatives.

155. As a direct and proximate result of Merck's anticompetitive conduct, Plaintiffs and members of the Class have been injured in their business or property by Merck's unlawful

monopolization of the Relevant Market. Plaintiffs and the other members of the Class have been forced to pay artificially high, supra-competitive prices for Mumps Vaccine of dubious efficacy, prices higher than they would have been absent Merck's unlawful monopolization of the Relevant Market.

SECOND CLAIM FOR RELIEF
Violation Of State Consumer Protection Laws
(On Behalf of Plaintiffs And The State Consumer Protection Subclass)

156. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Consolidated Amended Complaint.

157. This claim, which is asserted on behalf of the Plaintiffs and the members of the State Consumer Protection Subclass, pleads claims for violations of the consumer protection statutes of the following states: Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Kansas, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Virginia and Washington.

158. The consumer protection laws of the following states have enacted statutes designed to protect against false advertising and/or unfair, deceptive, fraudulent, and/or unconscionable acts or practices in the conduct of trade or commerce, and that further allow Plaintiffs and the members of the State Consumer Protection Subclass to bring private and/or class actions. These statutes are identified as follows:

- (a) Alaska Unfair Trade Practices and Consumer Protection Act, Alaska Statute § 45.50.471 *et seq.*;
- (b) Arizona Consumer Fraud Act, Arizona Revised Statute Annotated § 44-1521 *et seq.*;

- (c) Arkansas Deceptive Trade Practices Act, Arkansas Code § 4-88-101 *et seq.*;
- (d) California Unfair Competition Law, California Business and Professions Code § 17200 *et seq.*;
- (e) Colorado Consumer Protection Act, Colorado Revised Statute § 6-1-101 *et seq.*;
- (f) Connecticut Unfair Trade Practices Act, Connecticut General Statute § 42-110a *et seq.*;
- (g) Delaware Consumer Fraud Act, Delaware Code, title 6, § 2511 *et seq.*;
- (h) Florida Deceptive and Unfair Trade Practices Act, Florida Statute Annotated § 501.201 *et seq.*;
- (i) Idaho Consumer Protection Act, Idaho Code Annotated § 48-601 *et seq.*;
- (j) Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS § 505/1 *et seq.*;
- (k) Kansas Consumer Protection Act, Kansas Statute Annotated § 50-626 *et seq.*;
- (l) Michigan Consumer Protection Act, Michigan Compiled Laws Annotated § 445.901 *et seq.*;
- (m) Minnesota Prevention of Consumer Fraud Act, Minnesota Statute Annotated § 325F.68 *et seq.*;
- (n) Nebraska Consumer Protection Act, Nebraska Revised Statute § 59-1601 *et seq.*;

- (o) Nebraska Uniform Deceptive Trade Practices Act, Nebraska Revised Statute § 87-301 *et seq.*;
- (p) Nevada Trade Regulation and Practices Act, Nevada Revised Statute § 598.0903 *et seq.*;
- (q) New Hampshire Consumer Protection Act, New Hampshire Revised Statute § 358-A:1 *et seq.*;
- (r) New Jersey Consumer Fraud Act, New Jersey Statute Annotated § 56:8-1 *et seq.*;
- (s) New Mexico Unfair Practices Act, New Mexico Statute Annotated § 57-12-1 *et seq.*;
- (t) New York Deceptive Acts and Practices Act, New York General Business Law § 349 *et seq.*;
- (u) North Dakota Consumer Fraud Act, North Dakota Century Code § 51-15-01 *et seq.*;
- (v) Ohio Deceptive Trade Practices Act, Ohio Revised Code Annotated § 4165.01 *et seq.*;
- (w) Oklahoma Consumer Protection Act, Oklahoma Statute Annotated, title 15, § 751 *et seq.*;
- (x) Virginia Consumer Protection Act, Virginia Code Annotated § 59.1-196 *et seq.*; and
- (y) Washington Consumer Fraud Act, Washington Revised Code § 19.86.010 *et seq.*.

159. Each of the Plaintiffs seeking recovery under this claim and each member of the State Consumer Protection Subclass is a consumer, purchaser or other person entitled to the protection of the consumer protection laws identified in ¶ 158.

160. Merck is a supplier or other person within the meaning of the consumer protection laws identified in ¶ 158.

161. Mumps Vaccine constitutes a good, product, merchandise or other subject to which the consumer protection laws identified in ¶ 158 apply.

162. Merck's conduct, as set forth in more detail above, violates the consumer protection laws identified in ¶ 158.

163. Specifically, as alleged herein, Merck engaged in false advertising and/or unfair, deceptive, fraudulent and/or unconscionable acts or practices in the conduct of trade or commerce by making false or misleading statements regarding the efficacy of Mumps Vaccine and by concealing or failing to disclose that Mumps Vaccine was significantly less efficacious than marketed.

164. Merck engaged in the conduct alleged herein, even though it knew or reasonably should have known that Mumps Vaccine did not have a 95 percent efficacy rate. Indeed, Mumps Vaccine is not 95 percent effective.

165. Information regarding the true efficacy of Mumps Vaccine was not reasonably known to Plaintiffs and the members of the State Consumer Protection Subclass.

166. Merck intended to mislead, or recklessly or negligently misled, the Plaintiffs and the members of the State Consumer Protection Subclass and intended that the Plaintiffs and the members of the State Consumer Protection Subclass rely on its misrepresentations and omissions in purchasing and using Mumps Vaccine.

167. Plaintiffs and the members of the State Consumer Protection Subclass relied (or should be presumed to have relied) upon Merck's misrepresentations and omissions in purchasing and using Mumps Vaccine. The Plaintiffs and the members of the State Consumer Protection Subclass would not have purchased or used Mumps Vaccine had they known the truth.

168. As a direct and proximate result of Merck's misrepresentations and omissions, the Plaintiffs and the members of the State Consumer Protection Subclass were damaged in an amount to be proven at trial.

169. Plaintiffs and the members of the State Consumer Protection Subclass are entitled to recover actual compensatory and/or statutory damages, as well as attorneys' fees and costs of suit, pursuant to the consumer protection laws and other applicable laws.

THIRD CLAIM FOR RELIEF
Breach Of Contract
(On Behalf Of Plaintiffs And The Class)

170. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Consolidated Amended Complaint.

171. Merck entered into a contract to provide Mumps Vaccine to Plaintiffs and the members of the Class. The terms of that contract include the promises or affirmations of fact regarding the purported 95 percent efficacy rate made by Merck on the package inserts of Mumps Vaccine and through its marketing and promotion of Mumps Vaccine. This product labeling and advertising became part of the basis of the bargain, and is part of a standardized contract between Plaintiffs and the members of the Class on one hand, and Merck on the other hand.

172. Merck made its above-described representations intending that the representations would form the basis of the bargain between Plaintiffs and the members of the Class on the one hand, and Merck on the other and the representation did, in fact, form the basis of the bargain.

173. All conditions precedent to Merck's liability under its contracts with Plaintiffs and the members of the Class have been performed by Plaintiffs and the members of the Class when they purchased Mumps Vaccine for its ordinary purpose.

174. Merck breached these contracts because Mumps Vaccine does not have the 95 percent efficacy rate represented by Merck, and is in fact far less efficacious than represented by Merck.

175. As a direct, legal and proximate result of Merck's breach of contract, Plaintiffs and the members of the Class were damaged in the amount of the purchase price they paid for Mumps Vaccine in addition to such incidental and consequential damages suffered as a result.

FOURTH CLAIM FOR RELIEF
Violation Of Pennsylvania's Express Warranty Law, PA. STAT. ANN. TIT. 13, § 2313
(On Behalf Of Plaintiffs And The Class)

176. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Consolidated Amended Complaint.

177. This claim alleges breaches of express warranty under Section 2-313 of the Uniform Commercial Code ("UCC") as enacted in Pennsylvania. The Plaintiffs bring this claim individually and on behalf of the members of the Class.

178. At all times relevant hereto, Merck was a merchant within the meaning of the Pennsylvania Uniform Commercial Code because Merck deals in the goods which are the subject of this Consolidated Amended Complaint, i.e., Mumps Vaccine, and Merck otherwise holds itself out as having knowledge or skill peculiar to Mumps Vaccine.

179. Plaintiffs and the members of the Class are in privity with Merck because Merck sells Mumps Vaccine directly to Plaintiffs and the members of the Class.

180. Plaintiffs and the members of the Class formed a contract with Merck at the time they purchased Mumps Vaccine. The terms of that contract include the promises or affirmations of fact regarding the purported 95 percent efficacy rate made by Merck on the package inserts of Mumps Vaccine and through its marketing and advertising of Mumps Vaccine. This product labeling and advertising, of which Plaintiffs and the members of the Class were aware, constitutes express warranties and became part of the basis of the bargain, and is part of a standardized contract between Plaintiffs and the members of the Class on one hand, and Merck on the other hand.

181. Merck made its above-described representations intending that the representations would form the basis of the bargain between Plaintiffs and the members of the Class on one hand, and Merck on the other and the representation did, in fact, form the basis of the bargain.

182. In the alternative, Merck made the above-described representations to induce Plaintiffs and the members of the Class to rely on the representations and they each did so rely (and should be presumed to have relied) on Merck's representations as a material fact in their decision(s) to purchase Mumps Vaccine.

183. All conditions precedent to Merck's liability under this contract have been performed by Plaintiffs and the members of the Class when they purchased Mumps Vaccine for its ordinary purpose.

184. Under the Uniform Commercial Code of Pennsylvania, and in other states in which Merck markets and sells Mumps Vaccine, there exists an express warranty. *See* PA. STAT. ANN. TIT. 13, § 2313.

185. Merck breached this express warranty because Mumps Vaccine does not have the 95 percent efficacy rate represented by Merck, and is in fact far less efficacious than represented by Merck.

186. As a direct, legal and proximate result of Merck's breach of its express warranties, Plaintiffs and the members of the Class were damaged in the amount of the purchase price they paid for Mumps Vaccine in addition to such incidental and consequential damages suffered as a result.

187. Within a reasonable time after they knew or should have known of such breach, Plaintiffs, on behalf of themselves and the members of the Class, placed Merck on notice thereof.

FIFTH CLAIM FOR RELIEF

Violation Of Pennsylvania's Implied Warranty Law, PA. STAT. ANN. TIT. 13, § 2314 (On Behalf Of Plaintiffs And The Class)

188. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Consolidated Amended Complaint.

189. This claim alleges breaches of implied warranty under UCC § 2-314 as enacted, in whole or in substantial part, in Pennsylvania. The Plaintiffs bring this claim individually and on behalf of members of the Class.

190. At all times relevant hereto, Merck was a merchant within the meaning of the Pennsylvania Uniform Commercial Code because Merck deals in the goods which are the subject of this Consolidated Amended Complaint, i.e., Mumps Vaccine, and Merck otherwise holds itself out as having knowledge or skill peculiar to Mumps Vaccine.

191. Plaintiffs and the members of the Class suffered damages as a result of the use of Mumps Vaccine.

192. Plaintiffs and the members of the Class are in privity with Merck because Merck sells Mumps Vaccine directly to Plaintiffs and the members of the Class.

193. By placing Mumps Vaccine in the stream of Commerce, Merck impliedly warranted to Plaintiffs and the Class that Mumps Vaccine was of merchantable quality in that it would pass without objection in the trade, and was fit for the ordinary purpose for which it was to be used, and conformed to the promises or affirmations of fact regarding its purported 95 percent efficacy rate made on the package insert or as otherwise promoted, marketed, and/or advertised.

194. Under the Uniform Commercial Code of Pennsylvania, and in other states in which Merck markets and sells Mumps Vaccine, there exists an implied warranty of merchantability and fitness for a particular purpose. *See* PA. STAT. ANN. TIT. 13, § 2314.

195. Merck breached the implied warranty of merchantability at the time of sale because Mumps Vaccine would not pass without objection in the trade, was not fit for the ordinary purpose for which Mumps Vaccine was to be used, and did not conform to the promises or affirmations of fact made on the package insert or as otherwise promoted, marketed and/or advertised, in that Mumps Vaccine is not 95 percent efficacious, and is in fact far less efficacious than represented by Merck.

196. As a result of the breach of implied warranties, the Plaintiffs and the members of the Class have been directly and proximately damaged in the amount of the price they paid for Mumps Vaccine, and/or such incidental and consequential damages suffered thereby, in an aggregate amount to be proven at trial.

197. Within a reasonable time after they knew or should have known of such breach, the Plaintiffs, on behalf of themselves and the members of the Class, placed Merck on notice thereof.

SIXTH CLAIM FOR RELIEF
Unjust Enrichment
(On Behalf Of Plaintiffs And The Class)

198. Plaintiffs incorporate and reallege, as though fully set forth herein, each and every allegation set forth in the preceding paragraphs of this Consolidated Amended Complaint.

199. Plaintiffs and the members of the Class, in addition or in the alternative to the claims alleged above in the Third, Fourth, and Fifth Claims for Relief, on behalf of themselves and the members of the Class, bring this claim individually and on behalf of the members of the Class.

200. By engaging in the conduct described in this Consolidated Amended Complaint, Merck has knowingly obtained benefits from Plaintiffs and the members of the Class under circumstances such that it would be inequitable and unjust for Merck to retain them. Merck has been unjustly enriched by marketing and selling its Mumps Vaccine at inflated, anticompetitive, monopoly prices to Plaintiffs and the members of the Class.

201. Merck has collected payments for Mumps Vaccine from Plaintiffs and the members of the Class that vastly exceed the payments to which Merck was entitled as a matter of law. In exchange for these payments, and at the time they made these payments, Plaintiffs and the Class expected that Mumps Vaccine was 95 percent effective. It was not.

202. As a direct and proximate result of Merck's deceptive and anticompetitive conduct, Plaintiffs and the members of the Class have been injured in their business or property by Merck's monopolization of the Relevant Market. Plaintiffs and the members of the Class have been forced to pay artificially high, supra-competitive prices for Mumps Vaccine, prices higher than they would have paid absent Merck's monopolization of the Relevant Market through its deceptive and wrongful conduct.

203. Thus, Merck will be unjustly enriched if permitted to retain the full amount paid to it by Plaintiffs and the members of the Class.

204. Plaintiffs and the members of the Class are therefore entitled to an award of compensatory and punitive damages in an amount to be determined at trial or to the imposition of a constructive trust upon the wrongful profits obtained by, revenues obtained by, and benefits conferred upon Merck as a result of its wrongdoing and the payments made by Plaintiffs and members of the Class.

205. Plaintiffs and the members of the Class have no remedy at law to prevent Merck from continuing the inequitable conduct alleged herein and the continued unjust retention of the payments made to Merck by Plaintiffs and the members of the Class.

PRAYER FOR RELIEF

Accordingly, Plaintiffs, on behalf of themselves and the Class members, seek judgment as follows:

- (a) An order certifying this action as a class action under Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, appointing Plaintiffs as Class Representatives and their counsel of record as Class Counsel;
- (b) A declaration that Merck's conduct is in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;
- (c) A declaration that Merck's conduct is in violation of state consumer protection laws;
- (d) A declaration that Merck breached its contracts with Plaintiffs and the members of the Class;

- (e) A declaration that Merck's conduct is in violation of Pennsylvania warranty laws;
- (f) A declaration that Merck was unjustly enriched by its unlawful conduct;
- (g) Restitution and/or damages to Plaintiffs and the Class members for the purchase of Mumps Vaccine;
- (h) Treble damages under the antitrust laws, as well as actual damages, statutory damages, punitive damages, and such other relief as provided by the statutes cited herein;
- (i) Equitable relief in the form of restitution and/or disgorgement of all unlawful or illegal profits received by Merck as a result of the anticompetitive conduct alleged in herein;
- (j) Injunctive relief barring Merck from making further misrepresentations regarding the efficacy of its Mumps Vaccine;
- (k) Pre-judgment and post-judgment interest on monetary relief awarded;
- (l) The costs of bringing this suit, including reasonable attorneys' fees; and
- (m) All other relief to which Plaintiffs and members of the Class may be entitled which the Court deems proper.

JURY DEMAND

Pursuant to Rule 38(a) of the Federal Rules of Civil Procedure, Plaintiffs respectfully demand a trial by jury.

Dated: September 20, 2012

Respectfully submitted,

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